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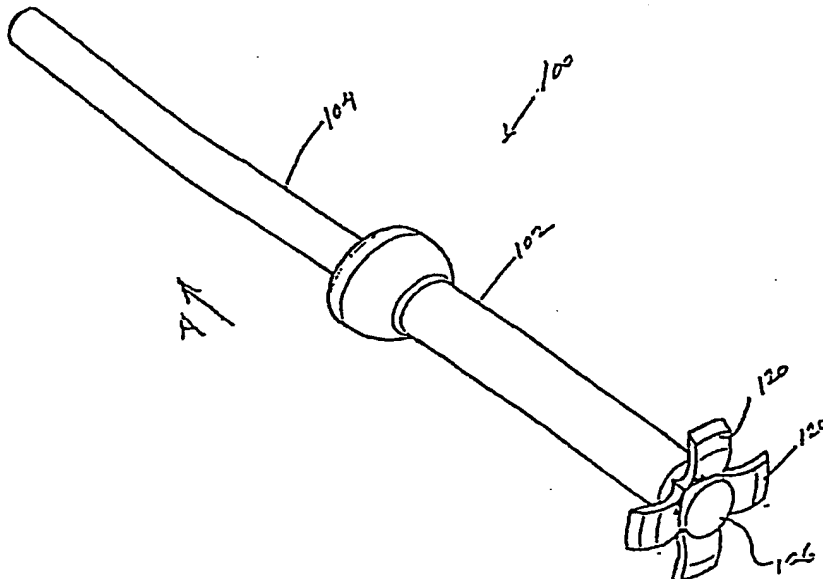
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(54) Title: ORTHOPEDIC/NEUROSURGICAL SYSTEM AND METHOD FOR SECURING VERTEBRAL BONE FACETS



(57) Abstract: A method for stabilizing adjacent vertebra is accomplished by use of a rivet assembly configured to extend between adjacent superior and inferior vertebra through a facet joint so that the distal end of the rivet assembly terminates at the base of superior articular process of the inferior vertebra.

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ORTHOPEDIC/NEUROSURGICAL SYSTEM AND METHOD FOR SECURING
VERTEBRAL BONE FACETS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application is based on and claims priority to U.S. Provisional Application 60/343,810 filed December 27, 2001.

BACKGROUND

1. **Technical Field**

[0002] The present disclosure relates to bone fastener assemblies and, more specifically to a rivet assembly for use in stabilizing facets of adjacent vertebrae to one another. The present disclosure also relates to a fastening tool and, more particularly, to a rivet crimping device for crimping a rivet assembly according to the present disclosure. In addition, the present disclosure relates to a bone stabilization method and, more particularly to a method for stabilization of adjacent vertebrae to one another using the rivet assembly and rivet crimper according to the present disclosure.

2. **Background of Related Art**

[0003] It is often necessary to fix the facet joints of adjacent vertebrae to one another or to attach objects (e.g., bone plates, bone grafts, etc.) to a bone itself. For example, in repairing a fractured or damaged vertebra, it is often necessary to stabilize individual vertebrae in order to promote proper healing. Stabilization is often accomplished by fixing one vertebra to adjacent vertebrae or by using a bone plate, or pedicle screw and rod system, to interconnect adjacent or a series of vertebrae to one another.

[0004] Prior art techniques often utilize screws to secure vertebrae or bone to one another or to secure a plate and/or rods between individual vertebrae or between

individual bones. In order to more securely anchor a screw into the vertebrae, bicortical placement of the screw into the bone is recommended. In other words, the screw is to penetrate through the cortex layer that is adjacent to the bone plate which is to be attached, then penetrate through the cancellous tissue in the interior of the bone and finally, penetrate into the opposite cortex layer on the opposite side of the bone.

[0005] Entering a bone is an invasive procedure that sometimes, based on the severity of problem which is encountered by an operating surgeon, requires that a screw penetrate through the opposite cortex layers. Accordingly, known screws have an elongated structure capable of bicortical purchase, otherwise the screws may loosen and fail to securely couple the plate to the bone or vertebrae.

[0006] Another known method is the use of pedicle screws for stabilizing adjacent vertebrae as well as for monosegmental or multisegmental fixation of a spinal column. Such screws typically do not obtain bicortical purchase and are therefore more susceptible to loosening. To help reduce this risk, the longest and largest size screw that can be safely inserted into the dense cancellous bone of the pedicle is used to maximize bone purchase. A typical pedicle screw includes a threaded portion and a receiver portion rigidly connected thereto at the head end of the screw. In use, several pairs of such screws are threaded into the vertebral bodies of the adjacent vertebra on either side of the spinal column through the pedicles. The respective receiver portions comprise receiving slits wherein a respective rod is passed through these receiving slits in the right and left hand group of pedicle screws. Thereafter, the rod is fixed to the respective receiver portion by means of fastening devices.

[0007] It is a drawback of this solution that it is difficult to rigidly insert screws through the pedicles on into the vertebral bodies and at the same time position the pedicle screws in two planes in exactly such a manner that the axes of the receiving slits in the receiver parts in the vertical columns align such that the rod may be passed through the receiving slits without distortion of the screws. Even with the advent of polyaxial screws, alignment of the receiving slits and contouring the rods to fit these slits remain a time

consuming process. A further drawback is the difficulty in properly positioning the screws within the pedicles. This takes much skill on the part of the surgeon. Compromising the integrity of the cortical walls of the pedicle as well as further penetration into the vertebral body of the vertebra could lead to neurological complications and eventual implant loosening. Additionally, the implantation of a pedicle screw system is a very invasive procedure, whereby a large incision is made to expose multiple vertebral levels. This is largely due to the fact that the pedicles of adjacent vertebrae are not themselves directly adjacent, thus the need for the rod to interconnect the pedicle screws inserted into the vertebrae.

[0008] Still another drawback is that the holding power of pedicle screws greatly depends on the length and size of screw used. Increasing the length and size of a screw improves its holding power. However, as discussed above, using such screws that extend through the pedicle on into the vertebral bodies results in a more invasive and time-consuming procedure.

[0009] Furthermore, under normal circumstances, intervertebral discs support approximately 70-80% of axial loads imposed upon the lumbar spine, whereas the rest of such axial loads fall on spinal structures including, among others, the facet joints. As a rule, natural distribution of axial loads is, however, disturbed as a result of implantation surgery. Typically, the pedicle screws carry axial loads in excess of 20-30%. One of the reasons for such a deviation from the natural distribution is the concern that unless the vertebral motion segment to be fused is not adequately immobilized, fusion will not occur. As a result, rigid stabilization systems are necessary for the initial healing. Hence, the pedicle screws, viewed as a structure, which is capable of supporting greater axial loads, are characterized by intentionally massive configurations capable of extending through the vertebral bodies of the adjacent vertebrae. Once fusion has occurred, the extensive pedicle screw hardware is usually left in the patient. There is concern that leaving so much 'foreign' material behind could be detrimental to the patient. Finally,

there is also a concern that existing pedicle screw systems may in fact be more rigid than necessary for a fusion to occur, and that a less rigid system that allows more 'normal' load sharing conditions may be preferable.

[0010] It is, therefore, desirable to provide a simpler, less invasive method of posteriorly stabilizing adjacent vertebra to be fused, as well as an instrumentation system configured to carry out such a method.

SUMMARY OF THE INVENTION

[0011] Consonant with the objectives of the present invention, an instrumentation system is configured to fuse the facet joints bridging adjacent superior and inferior vertebrae.

[0012] The function of the facet joint is to guide vertebral motion and to resist compression, rotation and shear forces. Unless traumatized or degenerated, the facet joints offer a strategically advantageous location for receiving supporting structures configured to stabilize adjacent vertebrae to be fused. This is because the facets themselves form a joint, which links adjacent vertebrae.

[0013] In accordance with one aspect of the invention, the inventive instrumentation system includes a rivet assembly shaped and dimensioned to penetrate through a facet joint and thus connect the superior and inferior vertebrae to be fused. The rivet assembly advantageously is configured so as to have its distal end terminate within the base of the superior articular process of the inferior vertebra without further penetration on into the vertebral body thereof.

[0014] Thus, one of the advantages of the inventive rivet assembly is that its structure is more compact and less massive than many of the known structures of bone fasteners in general and, particularly, pedicle screws. Accordingly, the rivet assembly configured in accordance with the invention is less rigid, allowing a more 'normal' load sharing condition that may be favorable for fusion.

[0015] In a particular advantageous embodiment of the instrumentation system, the rivet assembly is dimensioned so that when its recessed distal end expands, multiple separate leafs, constituting the distal end, engage the cancellous bone at the base of the superior articular process, and not even its opposite cortex layer, let alone the vertebral body. Thus, the inventive instrumentation system is calibrated to minimally invade a vertebral structure without, however, compromising the stability needed for fusion to occur. Without the need for the device to go all the way through the pedicle, the difficulties associated with the placement of pedicle screws is avoided. Compactness of the inventive rivet assembly allows the vertebral body of the inferior vertebra to remain intact.

[0016] In accordance with another aspect of the invention, the instrumentation system further includes a mandrel driving the distal end of the rivet assembly into engagement with the bone and configured to partially remain within the rivet assembly after its engagement with the bone.

[0017] Configuration of the mandrel includes a weakening portion allowing the body of the rivet to separate into multiple portions, the distal one of which remains rigidly attached within the rivet assembly. To simplify the manufacturing process, the mandrel is advantageously provided with an annular cross-section.

[0018] A further aspect of the invention relates to a rivet crimper specifically configured to engage the mandrel and to apply a pulling force thereto sufficient to pull it apart in a controlled manner, but not before the distal end of the rivet assembly has been driven into the engagement with the inferior vertebra.

[0019] In accordance with another aspect of the invention, a method of stabilizing adjacent vertebrae provides for engagement of the inventive rivet assembly with the inferior vertebrae. One particularly advantageous embodiment of the inventive method includes engagement of the rivet assembly with the cancellous bone at the base of the superior articular process of the inferior vertebrae. Limiting the penetration of the rivet

assembly by anchoring its distal end to the base of the superior articular process, represents a considerably less invasive approach than the known methods using pedicle screws which are designed to continue on through the entire length of the pedicle and purchase the structure of the vertebral body. In contrast with pedicle screw systems, which require four screws per fusion level, only two rivet assemblies through the facet joints are needed. The incision required to access this joint is considerably less than that required to access multiple pedicles for placement of a pedicle screw system.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0020] By way of example only, preferred embodiments of the disclosure will be described with reference to the accompanying drawings, in which:
- [0021] FIG. 1 is a perspective view of a rivet assembly according to the present disclosure;
- [0022] FIG. 2 is a side elevational view of the rivet assembly shown in FIG. 1;
- [0023] FIG. 3 is a perspective view of a rivet body according to the present disclosure;
- [0024] FIG. 3A is a perspective view of an alternative embodiment of the rivet body;
- [0025] FIG. 3B is a view of another alternative embodiment of the rivet body;
- [0026] FIG. 4 is a cross-sectional side elevational view of the rivet body shown in FIG. 3A taken along the longitudinal axis of the rivet assembly;
- [0027] FIG. 5 is an enlarged cross-sectional side elevational view of a distal end of the rivet body shown in FIG. 3A;
- [0028] FIG. 6 is a perspective view of a mandrel according to the present disclosure;
- [0029] FIG. 7 is an enlarged side elevational view of the mandrel shown in FIG. 6;
- [0030] FIG. 7A is a sectional view of the rivet assembly in accordance with one of the inventive embodiments of the invention, after having been deformed;
- [0031] FIG. 8 is a perspective view of the rivet assembly shown in FIG. 1, after having been deformed, according to the present disclosure;
- [0032] FIG. 9 is a side elevational view of the rivet assembly shown in FIG. 8;
- [0033] FIG. 10 is a perspective view of the rivet assembly shown in FIG. 1, after having been deformed, with the proximal end of the mandrel removed;

- [0034] FIG. 11 is a side elevational view of the rivet assembly shown in FIG. 10;
- [0035] FIG. 11A is a sectional view of the rivet assembly configured with an alternative embodiment;
- [0036] FIG. 11B is a perspective view of still another embodiment of the inventive rivet assembly;
- [0037] FIG. 12 is a perspective view of a rivet crimper configured in accordance with the invention;
- [0038] FIG. 13 is a side elevational view of the rivet crimper shown in FIG. 12;
- [0039] FIG. 14 is a cross-sectional view of the rivet crimper shown in FIG. 13;
- [0040] FIG. 15 is an enlarged view of the nose portion of the rivet crimper shown in FIG. 14 with the rivet assembly inserted within the nose and the handles of the rivet crimper in the open position;
- [0041] FIG. 16 is an enlarged view of the nose portion of the rivet crimper shown in FIG. 14 with the handles of the rivet crimper squeezed together;
- [0042] FIG. 17 is an enlarged view of the nose portion of the rivet crimper shown in FIG. 14 after the handles of the rivet crimper have returned to the open position, and the rivet body and distal portion of the shaft of the mandrel have separated from the proximal portion of the shaft of the mandrel;
- [0043] FIG. 18 is an enlarged view of the nose portion of the rivet crimper shown in FIG. 14 after the nose of the rivet crimper has been twisted inwardly thereby pushing the jaws inwardly in order to release the proximal end of the shaft of the mandrel;
- [0044] FIG. 19 is an enlarged view of the nose portion of the rivet crimper shown in FIG. 14 with the proximal end of the shaft removed therefrom;

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0045] A rivet assembly 100, as shown in FIGS. 1-11, is used in a variety of spinal implantation methods and is configured as a stabilization device primarily directed to connect inferior and superior articular processes of superior and inferior adjacent vertebrae, respectively. The rivet assembly 100 can be used as supplemental posterior stabilization in a circumferential or 360 degree fusion or as a stand-alone device for cases with slight posterior instability. Advantageously, the rivet assembly is shaped and

dimensioned for use with a transfacet method of implantation where the distal end 120 of the assembly remains buried inside cancellous bone. In contrast to various types of pedicle screws, the inventive rivet assembly 100 is dimensioned to allow a minimal invasion into the pedicle. Furthermore, because the rivet assembly 100 is less rigid than a pedicle screw system, the distribution of axial forces between an implanted intervertebral body and rivet assembly better approximates the natural distribution of these forces between intervertebral discs and supporting structures. The rivet assembly 100 can also be inserted successfully using other methods. One such method is a transfacet method, where the distal end can penetrate outside the cortical bone. Still another method is a translaminar method, where the distal end 120 of the rivet assembly enters the base of the spinous process, continues through the lamina on the contralateral side, on into the base of the transverse process. Finally, a percutaneous approach can be combined with the aforementioned methods and performed in association with the inventive rivet assembly 100.

[0046] Referring initially to FIGS. 1 and 2, a rivet assembly according to the present disclosure is generally depicted as 100. The rivet assembly 100 includes a cylindrical rivet body 102 and an elongate mandrel 104 slidably disposed within and extending through rivet body 102.

[0047] As seen in FIGS. 1-5, rivet body 102 includes a shank 106 having a head 108 formed at a proximal end thereof, a deformable tip 110 formed at a distal end thereof and a through bore 112 extending the entire length thereof. Head 108 includes a body portion 114 having a larger diameter than shank 106 and a tapered forward portion 116 configured to create a smooth interface between head 108 and shank 106. As seen in further detail in FIG. 5, deformable tip 110 includes a plurality of radially spaced and longitudinally extending throughslits 118 thereby defining a plurality of deformable semi-circular webs or leaf portions 120, wherein each leaf portion 120 includes a rounded frontal lip 122. Slits 118 may or may not be evenly spaced from one another. The leafs

or webs 120 are configured to engage the bone, preferably the cancellous bone, at the base of the superior articular process of the inferior vertebra, as will be explained herein below.

[0048] Alternatively, as illustrate in FIG. 3A, the shank 106 may have a textured 119 outer surface to better engage the bone. As shown in FIG. 3A, the proximal end of each slit 118 may also have additional relief slits 121 of varying shape and sizes.

[0049] In accordance with yet another configuration, as illustrated in FIG. 3B, the shank 106 may have a weakened portion spaced at a distance from both distal and proximal ends of the rivet body. The portion is provided with a plurality of radially spaced slits 121 defining therebetween a plurality of webs 123. Similarly to the leafs 120, the webs 123 are configured to expand radially outwards to engage the bone, as will be better discussed in reference to FIG. 11A.

[0050] As seen in FIGS. 6 and 7, mandrel 104 includes an elongate shaft 124 having an enlarged head 126 formed at a distal end thereof. The diameter of shaft head 126 approximately corresponds to an outer diameter of shank 106 of rivet body 102 and is provided with an annular rounded proximal surface 128 for providing a smooth transition between the enlarged head 126 and the shaft 124. Elongate shaft 124 of mandrel 104 is further provided with an annular break-off groove 130 formed therearound. Annular break-off groove 130 defines a zone of weakening whereby when shaft 124 of mandrel 104 is pulled through rivet body 102, a proximal end of shaft 124 will separate from a distal end of shaft 124 at the location of break-off groove 130. Between enlarged head 126 and groove 130, shaft 124 is provided with a roughened surface 132 (e.g., knurling, longitudinal grooves, annular rings, helical ridges etc.) completely encircling shaft 124. Roughened surface 132 functions to provide a frictional fit with the interior surface of shank 106 of rivet body 102 along through bore 112 and act as a vibration-resistant mechanism to insure that the distal end of mandrel 104 does not come out of or become disengaged from rivet body 102 once rivet assembly 100 has been secured into place.

[0051] Alternatively, as shown in FIG. 7A, the shaft 124 of mandrel 104 could have an additional step 119 located on the distal end of the mandrel 104 and cooperating with a shoulder 117 formed on the inner surface of the rivet body 102. The shoulder 117 provides a physical stop for the step 119 of the mandrel 104 limiting the extent of its travel.

[0052] As shown in FIGS. 1, 2, 4, and 6, shaft 124 of mandrel 104 is positioned within through bore 112 of rivet body 102 such that the enlarged head 126 of mandrel 104 is adjacent to the deformable tip 110 of rivet body 102. Turning now to FIGS. 4-6 and 8-9, in operation, on pulling mandrel 104 in direction "A", through bore 112 of rivet body 102, rounded surface 128 of shaft 124 interacts with rounded lip 122 of deformable tip 110 such that leafs 120 spread outwardly away from mandrel 104 along radial slits 118 and cause leafs 120 to curl back towards rivet body 102. Finally, as seen in FIGS. 4, 6, 10 and 11, once a pulling force exceeding the tensile strength of the mandrel has been reached, the proximal end of shaft 124 will separate or break-off along groove 130 and distal end of shaft 124 will remain frictionally engaged within shank 106 of rivet body 102 due to the frictional coupling of the roughened surface 132 of mandrel 104 with the inner surface of rivet body 102. The distal end of the rivet body 102 can have the shoulder 117 configured to abut the step 119 (FIG. 4) of the mandrel to prevent its displacement through the rivet body.

[0053] FIG. 11A illustrates the rivet assembly having the rivet body 102 configured in accordance with the alternative embodiment shown in FIG. 3B. Multiple webs 123 constitute the weakened region of the rivet body 102. In addition, the distal end 125 of the rivet body 102 is threaded to threadingly engage a distal threaded end of the mandrel 100. As the mandrel 100 advances through the proximal end of the rivet body 102, the webs 123, defined between slits 121, deform to engage the bone, as shown in phantom lines in FIG. 11A. While the principle of the engagement is similar to the previously disclosed embodiment having the deformable distal end, instead of a tensile force, a sufficient external torque should be applied to the mandrel 100, which is configured similar to the above disclosed structure, to couple the components of the rivet assembly.

[0054] While the rivet assembly, as discussed above, has substantially the straight rivet body and mandrel, the components of the assembly may have a curved shape, as shown in FIG 11B.

[0055] Referring now to FIGS. 12 to 19, a rivet crimper according to the present disclosure is generally depicted as 200. Rivet crimper 200 includes a handle assembly 202 operatively coupled to a rivet crimping assembly 204. Handle assembly 202 includes a first handle 206 integrally formed with crimping assembly 204, a second handle 208 pivotally coupled to crimping assembly 204 and biasing means 210 disposed between the first and second handles 206 and 208 for maintaining handles 206 and 208 spaced from one another.

[0056] Crimping assembly 204 includes a nose 212 threaded on to the forward end of the crimping assembly 204 via threading means 214. Nose 212 includes a hollow rearward portion 216 and a mandrel shaft-receiving portion 218 which is co-axial with hollow rearward portion 216. Mandrel shaft receiving portion 218 has a diameter which is smaller than the diameter of the hollow rearward portion 216 thereby defining a shoulder 220.

[0057] Crimping assembly 204 further includes a cylinder body 222 slidably disposed within the hollow rearward portion 216, which cylinder body 222 includes frusto-conically shaped forward portion 224 having a smaller diameter opening proximate the shoulder 220 of the hollow rearward portion 216 and a larger diameter opening spaced a distance rearward therefrom. The frusto-conical forward portion 224 defines a first camming surface 226 against which the outer surfaces of jaws 228 contact and slide. The pair of jaws 228 include a pair of substantially parallel row of teeth 230, a forward portion 232 projecting from the forward portion 224 of cylinder body 222 and a chamfered rearward portion 234 defining a second camming surface 236.

[0058] Crimping assembly 204 further includes a plunger 238 having a forward

portion 240 configured and adapted to be threaded into or connected to a rearward portion of the cylinder body 222, a central body portion 242 and a rearward portion 244 pivotally connected to linkage 246 pivotally connected to the second handle 208.

[0059] The crimping assembly 204 also includes a piston 248 slidably disposed within the cylinder body 222 and biased via biasing means 250 toward the forward portion 224 of cylinder body 222. Piston 248 includes an angled forward surface 252 configured and adapted to engage the chamfered surface 236 of the pair of jaws 228. In this way, the angled forward surface 252 of the biased piston 248 presses against the camming surface 236 of the pair of jaws 228 to first keep the pair of jaws 228 aligned with each other and to second keep the outer surface of the first pair of jaws 228 pressed against the frusto-conical camming surface 226 of forward portion 224 of cylinder body 222 thereby squeezing the pair of jaws 228 together.

[0060] Use of rivet crimper 200 is as follows. Prior to loading rivet crimper 200 with a rivet assembly 100, handle assembly 202 is maintained in a spaced apart open position whereby the cylinder body 222 is maintained in a forward portion via plunger 238 and linkage 246 and by second keeping the nose 212 in a fully forward disposed position. Shoulder 220 of nose 212 keeps the pair of jaws 228 partially open (despite the biasing force of 250) to facilitate insertion of the rivet assembly.

[0061] Next, the proximal end of a mandrel shaft 124 of rivet assembly 100 is inserted into the mandrel shaft receiving portion 218 of nose 212. Rivet assembly 100 is inserted into the nose 212 until head 108 of rivet body 102 abuts against the tip of nose 212. To prevent any possibility of uncontrollable displacement of the tip of the mandrel shaft 124 towards the rear end of the rivet crimper 200 which would necessitate disassembly of the nose 212 after the rivet assembly has been placed in the facets, piston 248 is provided with a stop 215. Once shaft 124 is inserted past the mandrel shaft receiving portion 218, shaft 124 engages the pair of jaws 228. Shaft 124 is then inserted into the forward portion 232 of the pair of jaws 228 with a force sufficient to overcome the biasing force of biasing means 250. In this manner, the pair of jaws 228 slide

rearwardly against angled forward surface 252 thereby causing the pair of jaws 228 to become further spaced apart in order to accommodate shaft 124 therebetween. Once the insertion force for rivet assembly 100 is removed, the force created by the biasing means 250 pressing the piston 248 into the pair of jaws 228 forces the pair of jaws 228 forward along the first camming surface 226, pressing the rows of the teeth 230 into shaft 124 thereby gripping shaft 124 and preventing the removal of rivet assembly 100 from nose 212 of rivet crimper 200.

[0062] In order to deform rivet assembly 100, handle assembly 202 of rivet crimper 200 is squeezed together thereby drawing linkage 246 and plunger 238 rearwardly. As plunger 238 draws cylinder body 222 rearwardly through hollow rearward portion 216, the pair of jaws 228 gripping shaft 124 draw shaft 124 rearwardly through shank 106 of rivet body 102. As shaft 124 of mandrel 104 is drawn through shank 106 of rivet body 102, the rounded surface 128 of shaft 124 presses into the rounded lip 122 of deformable tip 110 such that leafs 120 spread outwardly away from mandrel 104 along radial slits 118 causing leafs 120 to curl back towards rivet body 102. Once the pulling force reaches a sufficient degree, the proximal end of shaft 124 of mandrel 104 will separate from the remainder of rivet assembly 100 and break-off along groove 130. The break-off groove 130 is positioned such that the distal portion of shaft 124 of mandrel 104 does not protrude out of head 108 of rivet body 102.

[0063] In order to remove the proximal portion that has broken off of shaft 124 from the pair of jaws 228, handle assembly 202 is first returned to the un-squeezed and open position. Nose 212 is then twisted inwardly about threading means 214 such that the overall length of rivet crimper 200 is shorter. Nose 212 is twisted until shoulder 220 in nose 212 contacts and presses against forward portion 232 of the pair of jaws 228 and then twisted further so as to force the pair of jaws 228 rearwardly against the biasing force created by the biasing means 250 and radially outward as a result of the interaction of the rearward chamfered surface 236 and the angled forward surface 252 of piston 248. By the pair of jaws 228 moving radially outward, the rows of teeth 230 release their grip from around the shaft 124 and the shaft 124 is able to be removed easily from the

mandrel shaft receiving portion 218 of nose 212.

[0064] Referring to FIGS. 1 to 19, the method of the present invention will now be described. In general, the method involves the insertion of the rivet assembly 100 starting from the posterior surface of the inferior articular process of the superior vertebra, crossing the facet joint, and on into the superior articular process of the inferior vertebra.

[0065] To secure the facets of the adjacent vertebrae to one another with rivet assembly 100 using rivet crimper 200 disclosed herein, the intended area of operation must first be exposed by entering a patient in accordance with standard surgical procedures. This typically involves a small midline (along the spine column) incision exposing the facets. After the facets of the vertebrae are exposed, the surgeon places a K-wire in the intended location and uses a cannulated drill to create a blind hole across the facet joint to the desired depth. In a preferred method, the drill goes through the inferior articular process of the superior vertebrae, across the facet joint, into the superior articular process of the inferior vertebrae ending at the base of the superior articular process such that the hole formed in the inferior vertebrae solely penetrates the upper cortical surface of the superior articular process and does not completely pass through the inferior vertebrae.

[0066] After removing the K-wire and the drill, the surgeon uses a depth gage to measure the depth of the hole and selects rivet assemblies 100 to be used based on their rivet body lengths, body diameters, head diameters, etc. Multiple diameter and length rivet assemblies are envisioned. It is evident that the diameter of each hole drilled is slightly larger than the diameter of each shank 106 so that the rivet body 102 is easily insertable within the hole. Next, the surgeon inserts the proximal end of shaft 124 of rivet assembly 100 into the mandrel shaft receiving portion 218 of rivet crimper 200 until head 108 of rivet body 102 abuts against the tip of nose 212.

[0067] The surgeon then inserts deformable tip end 110 of rivet body 102 through the

hole formed in the facets until head 108 of rivet body 102 rests against the outside of the inferior facet of the superior vertebrae. The surgeon then actuates rivet crimper 200 in the manner disclosed above. Rivet crimper 200 exerts a force on the shaft 124 of mandrel 104 so as to pull mandrel 104 through rivet body 102 thereby deforming leafs 120 of deformable tip 110 until shaft 124 of mandrel 104 separates along groove 130. The distal part of shaft 124 of mandrel 104 stays within the deformed rivet body 102. The proximal part of shaft 124 remains securely held by jaws 228 in nose 212 of rivet crimper 200. The deformation of leafs 120 secures rivet body 102 in place and the surgeon does not have to be concerned with retrieving the broken off shaft portion from the patient's body cavity.

[0068] Securing rivet assembly 100 with rivet crimper 200 requires very little effort on the part of the surgeon. The surgeon merely squeezes handle assembly 202 of rivet crimper 200 to actuate crimping assembly 204. Rivet crimper 200 does all of the work in securing the rivet assembly 100 in place.

[0069] When rivet assembly 100 is secured in place, the facets of adjacent vertebrae are clamped together between the head 108 and the deformed leafs 120 of deformable tip 110 of rivet body 102. The surgeon then adds bone graft to the appropriately decorticated areas to complete the fusion procedure.

[0070] Although the method described above for inserting the rivet assembly 100 is for an open surgical procedure, the insertion method can easily be adapted to a percutaneous approach. The percutaneous approach would begin with a small stab incision, directed generally perpendicular to the longitudinal direction of the spine column, through which a K-wire could be placed. A cannulated drill is then used to drill the appropriate sized hole over the K-wire. The drill can have a depth stop shaped like head 108 of the rivet body 102 such that the drill only creates holes up to a specific depth. Such depths can be made to specifically match designated lengths of the rivet assembly 100, thus eliminating the need for a depth gage. A sleeve is then placed over the drill. Spikes or other attachment means at the end of the sleeve ensure its position relative to

the bone. The drill and K-wire are removed. While loaded in the crimping assembly 200, the rivet assembly 100 can then be inserted through the sleeve into the hole. The crimping assembly 200 is then operated as described above, implanting the rivet assembly 100. The crimping assembly 200 is then withdrawn from the sleeve, and the sleeve is removed. The proximal part of shaft 124 can then be safely removed from jaws 228 in nose 212 of rivet crimper 200.

[0071] It is preferred to drill a blind hole toward the pedicle to keep the deformed webs 120 of rivet assembly 100 within the cancellous bone and keep the exposed rivet profile to a minimum. As mentioned above, however, other methods (transfacet, translaminar, etc.) where webs 120 deform inside or outside the bone (facet) are also envisioned.

[0072] Although the current technique describes using the rivet alone to stabilize the facets, it is envisioned that the rivet assembly 100 could be used with other components (i.e., plates, etc.), in other locations, and applications (i.e., trauma, etc.).

[0073] Additionally, arcuate rivet assemblies are also envisioned, which may allow the surgeon to more easily insert the rivets through the facets. With an arcuate rivet assembly, a flexible drill would be necessary to drill over a similarly curved K-wire.

[0074] It will be understood that various modifications may be made to the embodiments disclosed herein. It is envisioned to make the inventive rivet assembly from a variety of materials including, but not limited to, metals, such titanium, stainless steel, biodegradable, plastic or any material transparent when used in association with modern diagnostic procedures. The number and geometry of the slits in the rivet body can vary depending on the material properties of the rivet body and the manner of deformation desired. The size and the shape of the mandrel groove can also vary depending on the mandrel's material properties and the amount of deformation desired in the rivet body. In addition, the present disclosure relates to a peel type rivet, however, it is envisioned that a rivet undergoing an annular-ring-type deformation is also possible.

Moreover, it is envisioned that the outer surface of the rivet body can be roughened (e.g., knurled, grooved, spiked, etc.) in order to provide the rivet body with better holding power. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. The kit also includes an instrumentation/implant case specifically configured to contain variously shaped and dimensioned implants and rivets, as well as the inventive crimper assembly. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

What is claimed is

- 1 1. A method for stabilizing adjacent vertebrae, comprising the steps of:
2 inserting a rivet assembly through a hole in the posterior surface of inferior
3 articular process of one of the adjacent vertebrae through a facet joint;
4 terminating the advancement of the rivet assembly before going through the
5 pedicle and reaching a vertebral body of the other vertebra; and
6 applying a pulling force to the rivet assembly to engage a portion thereof with
7 other vertebra, thereby preventing relative displacement between the adjacent vertebra
8 and the rivet assembly.
1
- 1 2. The method of claim 1, wherein the step of inserting the rivet assembly is
2 performed either before or after an implantation of interbody device between the adjacent
3 vertebrae.
1
- 1 3. A method for stabilizing adjacent superior and inferior vertebrae utilizing a
2 orthopedic/neurosurgical system, comprising:
3 a hollow rivet body provided with a weakened portion,
4 a mandrel configured to traverse the hollow rivet body, and
5 a rivet crimper configured to engage and apply a pulling force to a proximal end
6 of the mandrel sufficient to displace the mandrel through the rivet body so that the
7 weakened portion thereof expands radially outwards to engage at least one of the facets,
8 the method comprising the steps of:
9 drilling a hole through an inferior articular process of the superior vertebrae,
10 across a facet joint, into a superior articular process of the inferior vertebrae ending at a
11 base of the superior articular process such that the hole formed in the inferior vertebrae
12 solely penetrates the upper cortical surface of the superior articular process and
13 terminates within the inferior vertebrae;
14 placing the rivet body traversed by the mandrel into the hole and applying the
15 pulling force to the proximal end of the mandrel so that the weakened portion of the rivet
16 body engages the inferior vertebra at a base of the superior articular process thereof.

1 4. The method of claim 3, further comprising the steps of providing a midline
2 incision directed generally parallel to a spine column through an area of interest and
3 drilling a hole through the inferior articular process of the superior vertebrae, across a
4 facet joint, into the superior articular process of the inferior vertebrae to receive the rivet
5 assembly.

1

1 5. The method of claim 4, further comprising the steps of providing a small stab
2 incision directed generally perpendicular to a spine column through an area of interest,
3 placing a K-wire through the incision, and creating the hole with a cannulated drill over
4 the K-wire to receive the rivet assembly.

1

1 6. The method of claim 5, wherein implanting the rivet assembly includes the steps
2 of:

3 placing a sleeve over the cannulated drill;
4 securing the sleeve to the superior vertebra; and
5 removing the drill and K-wire to insert the rivet assembly into the hole through
6 the sleeve.

1

1 7. A orthopedic/neurosurgical system, comprising a hollow rivet body configured to
2 extend through a facet joint to bridge an inferior articular process of a superior vertebra
3 with an inferior vertebra, the hollow rivet body having at least one of opposite proximal
4 and distal ends thereof operative to expand radially outwards from the rivet body to
5 engage the inferior vertebra.

1

1 8. The system of claim 7, wherein the hollow rivet body extends along a path to
2 have the distal end terminate upstream from a pedicle of the inferior vertebra, the hollow
3 rivet body being configured with spaced apart slits or slits terminating at a distance from
4 the proximal end of the rivet body and defining a plurality of multiple deformable webs,
5 the deformable webs being shaped and dimensioned to engage a cancellous or cortical
6 bone of the superior articular process of the inferior vertebra.

1

1 9. The system of claim 8, wherein the spaced apart recesses terminate at a distance
2 from the proximal and distal ends of the rivet body and spaced from one another at a
3 regular or irregular angle to define therebetween the plurality of webs, which are
4 configured to buckle up radially outwards to engage the bone at the base of the superior
5 articular process of the inferior vertebra.

1

1 10. The system of claim 8, wherein the spaced apart slits are formed on the distal end
2 of the rivet body and spaced from one another at a regular or irregular angle to define the
3 plurality of webs configured to engage the bone at the base of the superior articular
4 process of the inferior vertebra.

1

1 11. The system of claim 10, wherein the slits each have a relief portion formed at a
2 bottom of each slit and extending angularly outwards in opposite directions from the
3 recess and provided with an annular or polygonal cross-section.

1

1 12. The system of claim 7, wherein the rivet body has a head formed on the proximal
2 end and tapering towards the distal end to provide a smooth transitional region on
3 proximal end of the rivet body.

1

1 13. The system of claim 8, further comprising a mandrel configured to traverse the
2 rivet body to an engaging position, wherein the plurality of webs are expanded radially
3 outwards to engage the base of the superior articular process of the inferior vertebra.

1

1 14. The system of claim 13, wherein the mandrel has a threaded distal end threadingly
2 engaging the distal end of the rivet body in the engaging position, the mandrel having an
3 annular break-off groove providing separation between proximal and distal ends of the
4 mandrel in response to an external torque applied to the proximal end.

1

1 15. The system of claim 10, further comprising a mandrel configured to move
2 through the rivet body and having a distal end shaped to abut and deform the plurality of
3 webs radially outwards in response to a pulling force applied to a proximal end of the

4 mandrel, wherein the deformed webs engage the bone in the engaging position at the base
5 of the superior articular process of the inferior vertebra.

6

1

1 16. The system of claim 15, wherein the mandrel has an annular break-off groove
2 provided between the proximal and distal ends thereof and configured to separate the
3 proximal and distal ends of the mandrel in response to the pulling force exceeding the
4 mandrel's tensile strength.

1

1 17. The system of claim 16, wherein the mandrel is provided with an annular textured
2 region located between the annular break-off groove and the distal end of the mandrel
3 and configured to provide a frictional fit to ensure engagement between the distal end of
4 the mandrel and the rivet body after the proximal and distal ends of the mandrel have
5 been separated.

1

1 18. The system of claim 17, wherein the annular textured region is provided with
2 annular end formations extending radially from a periphery thereof and configured to
3 attach to an inner surface of the rivet body.

1

1 19. The system of claim 14, wherein the distal end of the mandrel is provided with a
2 step configured to abut against a shoulder, provided in the rivet body between the
3 proximal and distal ends thereof, in the engaging position of the webs.

1

1 20. The system of claim 18, wherein the rivet body and the mandrel are
2 complementary shaped and configured to be straight or curved.

1

1 21. The system of claim 17, further comprising a rivet crimper configured to receive
2 the proximal end of the mandrel and operative to apply the pulling force to the mandrel
3 sufficient to drive the mandrel relative to the rivet body.

1

1 22. The system of claim 21, wherein the rivet crimper includes
2 a handle assembly,

3 a nose displaceably mounted to the handle assembly and provided with a
4 frontward portion traversed by the distal end of the mandrel and a hollow rearward
5 portion, and

6 a crimping assembly extending within the nose and detachably engaging the
7 proximal end of the mandrel so that when the pulling force is applied to the mandrel, it
8 moves rearwards from a loading position, in which the head of the of the rivet body abuts
9 a tip of the forward portion of the nose, to a deployed position, in which the proximal and
10 distal ends of the mandrel are separated after the webs formed on the rivet body have
11 been displaced to the engaging position thereof.

1
1 23. The system of claim 22, wherein the hollow rearward and frontward portions of the
2 nose have a shoulder extending radially outwards from the frontward portion to the
3 hollow rearward portion, the crimping assembly being provided with:

4 a plunger coupled to the handle assembly and displaceable in response to
5 actuation of the handle assembly, and

6 a cylinder body coupled with the plunger and displaceable therewith in the
7 rearward portion of the nose in response to the application of the pulling force so that a
8 front end of the cylinder body is located in a close proximity to the shoulder of the nose
9 in the loading position of the mandrel and in a distant proximity to the shoulder in the
10 deployed position of the mandrel.

1
1 24. The system of claim 23, wherein the forward end of the cylinder body is provided
2 with a frustoconical inner front surface tapering towards the shoulder of the nose, the
3 crimping assembly further including

4 a plurality of jaws having inner surfaces and outer surfaces, which extend
5 complementary to and slidably engage the inner front surface of the cylinder body,

6 a piston slidable within the cylinder body and provided with a front surface
7 coupled to rear ends of the jaws, and

8 a spring extending in the cylinder body between and coupled with the plunger and
9 the piston so as to bias the jaws towards the shoulder.

1

1 25. The system of claim 24, wherein the inner surfaces of the jaws are spaced radially
2 apart to form a passage, configured to receive the proximal end of the mandrel, and each
3 have a row of teeth engaging the proximal end of the mandrel so that the piston, the jaws
4 and the mandrel move rearwards to the loading position of the mandrel, in which further
5 relative axial displacement between the jaws and the cylinder body is prevented.

1
1 26. The system of claim 25, wherein the cylinder body, the jaws, the mandrel, the
2 piston and the plunger are displaceable in response to application of the pulling force
3 generated by the handle assembly from the loading position to the deployed position of
4 the mandrel.

1
1 27. The system of claim 26, wherein the handle assembly has a pair of handles
2 pivotally attached to and resiliently biased away from one another so that when an
3 external force is applied to the handle assembly, the handles are displaceable towards one
4 another while generating the pulling force applied to the plunger.

1
1 28. The system of claim 27, wherein one of the handles of the handle assembly is
2 pivotally coupled to a linkage attached to the plunger so that pivotal displacement of the
3 one handle is translated into axial displacement of the plunger.

1
1 29. The system of claim 24, wherein the piston of the crimping assembly has a front
2 angled surface opposing to the rear ends of the jaws, each of which has an inner radial
3 surface extending complementary to and in contact with the front angled surface of the
4 piston during displacement of the mandrel to the deployed position in response to
5 actuation of the handle assembly.

1
1 30. The system of claim 29, wherein the jaws slide radially outwards along the front
2 angled surface of the piston to a release position thereof in response to actuation of the
3 handle assembly, wherein the proximal end of the mandrel is removable from the
4 crimping assembly.

1

1 31. The system of claim 22, wherein the nose and the handle assembly are provided
2 with outer and inner threads, respectively, matching one another to allow the nose to
3 rotate relative to the handle assembly between an outer position corresponding to the
4 deployed position of the mandrel and an inner position corresponding to the release
5 position of the jaws.

1
1 32. An orthopedic/neurosurgical system for stabilizing adjacent vertebral facets,
2 comprising:
3 a rivet assembly configured to extend through and to engage each of the adjacent
4 vertebral facets in an engaging position of the rivet assembly; and
5 a crimper coupled to the rivet assembly and operative to anchor the rivet assembly
6 in the engaging position in each of the vertebral facets, whereas, after the rivet assembly
7 has been anchored in the vertebrae vertebral facets, the rivet assemblies are interlinked.

1
1 33. The system of claim 32, wherein the crimper operates in
2 a first mode, wherein the rivet assembly is attachable to the crimper,
3 a second mode, wherein the crimper displaces the rivet assembly to the engaging
4 position in each of the facets of the adjacent vertebra, and
5 a third mode, wherein the rivet assembly is detachable from the crimper.

1
1 34. The system of claim 33, wherein the crimper includes a handle assembly and a
2 linkage assembly configured to switch the crimper between the first, second and third
3 modes, the linkage assembly comprising:
4 a nose coupled to the handle assembly and extending along an axis,
5 an actuator operatively connected to the handle assembly and configured to move
6 linearly in the nose in response to the actuation of the handle assembly, and
7 a plurality of jaws mounted in the nose and coupled to the actuator to provide
8 attachment, displacement and detachment of the rivet assembly in the first, second and
9 third modes of operation of the crimper, respectively.

1
1 35. The system of claim 34, wherein the handle assembly includes

2 two handles coupled pivotally to one another and displaceable about a first pivot
3 axis between an open position associated with the first mode of operation of the crimper
4 and a squeezed position corresponding to the second mode of operation of the crimper,
5 a resilient component coupled to and generating a spring force biasing the two
6 handles away from one another to the open position to provide the crimper with the first
7 mode of operation, wherein the rivet assembly is attached to the crimper, and the third
8 mode of operation, wherein the rivet assembly is detached from the crimping assembly.

1
1 36. The system of claim 35, wherein one of handles is threaded to the nose and the
2 other handle is so coupled to the linkage assembly that when an external force applied to
3 the handle assembly overcomes the spring force, pivotal motion of the other handle is
4 translated into axial motion of the actuator and the jaws.

1
1 37. The system of claim 36, wherein the actuator includes
2 a link pivotally mounted to the other handle about a second pivot axis spaced
3 from the first pivot axis and displaceable axially rearwards from the nose simultaneously
4 with displacement of the other handle from the open position to the squeezed positions of
5 the handle assembly,

6 a plunger fixed to the linkage and extending axially in the nose,
7 a piston spaced axially apart from the plunger and extending within the nose, and
8 a spring extending between and braced against the plunger and the piston so that a
9 force, generated by the spring, biases the piston towards the jaws to maintain continuous
10 contact therebetween during the first, second and third modes of operation of the crimper.

1
1 38. The system of claim 37, wherein the nose has a shoulder limiting displacement of
2 the jaws frontward in the open position of the handle assembly in the first and third modes
3 of operation of the crimper, the actuator including a cylinder body axially movable
4 between the plunger and the shoulder and having an inner annular surface slidably
5 engaged by the spring and radially juxtaposed with outer surfaces of the piston and jaws.

1
1 39. The system of claim 38, wherein the jaws are spaced radially apart to define an
2 axial passage, a front portion of the inner surfaces of the cylinder body and outer surfaces

3 of the jaws extending complementary to one another to maintain the jaws apart in the first
4 and third modes of operation of the crimper corresponding to the open position of the
5 handle assembly, in which the jaws press against the shoulder of the nose to have the
6 passage configured to receive and release the rivet assembly.

1
1 40. The system of claim 39, wherein rear surfaces of the jaws each are chamfered and
2 abut an angled front surface of the piston, the rivet assembly including
3 a hollow rivet, provided with an expandable distal end, and
4 a mandrel insertable through the hollow rivet and having a proximal end
5 extending through the passage and ending within a blind hole formed in the piston in the
6 first mode of operation of the crimper, wherein the proximal end of the mandrel is
7 engaged by rows of teeth formed on the jaws so that relative axial displacement between
8 the jaws and the mandrel is prevented in the first, second and third modes of operation of
9 the crimper.

1
1 41. The system of claim 40, wherein the jaws, the proximal end of the mandrel and
2 the piston are displaceable rearwards in response to the pulling force overcoming the
3 force of the spring as the handle assembly moves from the open position to the squeezed
4 position thereof,
5 a distal end of the mandrel is driving the distal end of the rivet to an engaging
6 position thereof, wherein a portion of the rivet is expanded to engage a respective
7 vertebrae facet.

1
1 42. The system of claim 38, wherein the nose, displaceable rearwards relative to the
2 handle assembly in the third mode of operation of the crimper after the handle assembly
3 has been returned to the open position, generates a releasing force guiding the chamfered
4 rear surface of the jaws radially outwards from the proximal end of the rivet along the
5 angled front surface of the piston so that the rivet assembly can be detached from the
6 crimper.

1
1 43. The system of claim 41, wherein the portion of the rivet is formed either on the
2 distal end of the rivet or between the distal and proximal ends thereof and has a plurality

3 of slits defining therebetween multiple webs, which are driven radially outwards as the
4 mandrel is drawn into the rivet.

1
1 44. The system of claim 43, wherein the mandrel is provided with an annular break-
2 off groove located between the proximal and distal ends of the mandrel and configured to
3 separate the proximal and distal ends of the mandrel in response to the pulling force.

1
1 45. An instrumentation kit for stabilizing adjacent vertebrae, comprising:
2 a plurality of rivet assemblies each configured to extend through a facet joint
3 between adjacent vertebrae; and
4 a crimper configured to engage each of the rivet assemblies and to generate a
5 force applied thereto and sufficient to deform a weakened portion of each rivet assembly
6 so that the rivet assembly anchors to one of the adjacent vertebrae.

1
1 46. The kit of claim 45, wherein the crimper includes a handle assembly displaceable
2 between open and squeezed positions and a crimping assembly actuated in response to
3 displacement of the handle assembly to operate in
4 a first mode, wherein the rivet assembly is attachable to the crimper,
5 a second mode, wherein the crimper drives the rivet assembly so as to lock the
6 rivet assembly in the one vertebra, and
7 a third mode, wherein the rivet assembly is releasable from the crimper.

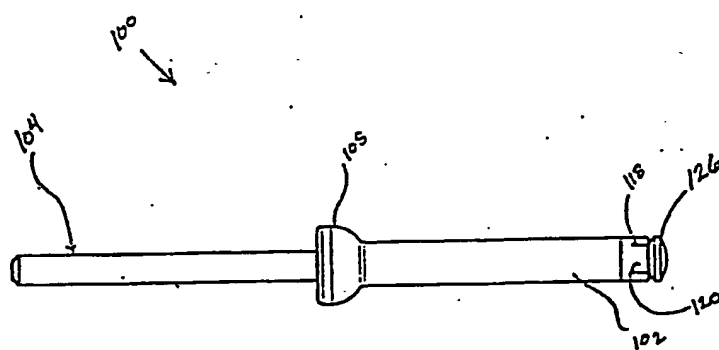
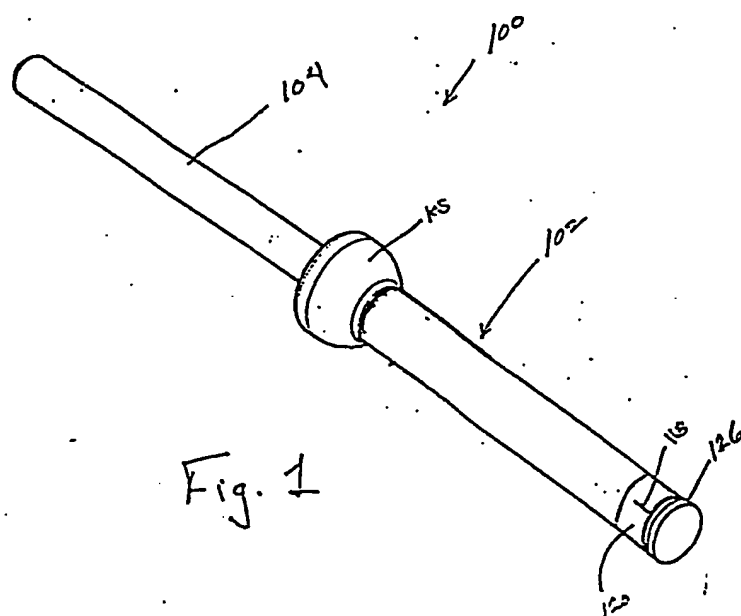
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1 47. The kit of claim 46, wherein the crimping assembly includes a plurality of jaws
2 configured to detachably engage the rivet assembly and displaceable linearly therewith as
3 the crimping assembly operates in the first and second modes of operation and
4 displaceable radially outwards from and releasing the rivet assembly on the third mode.

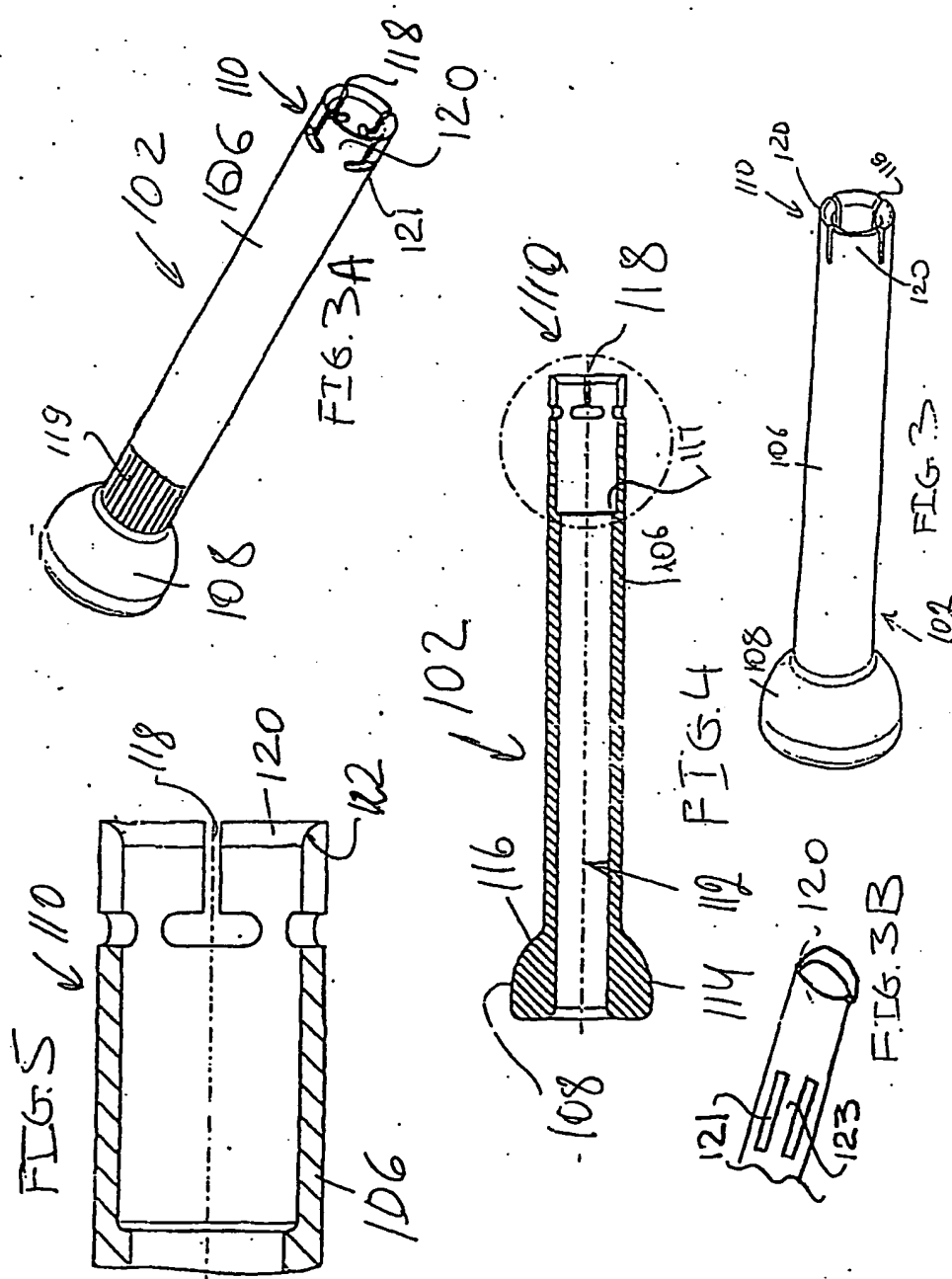
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1 48. The kit of claim 47, wherein the rivet assembly includes
2 a hollow rivet extending through the facets of adjacent vertebra and having a
3 distal portion defining the distal end of the rivet assembly, and
4 a mandrel insertable through the hollow rivet and configured to
5 detachably engage the crimping assembly in the first mode of operation,

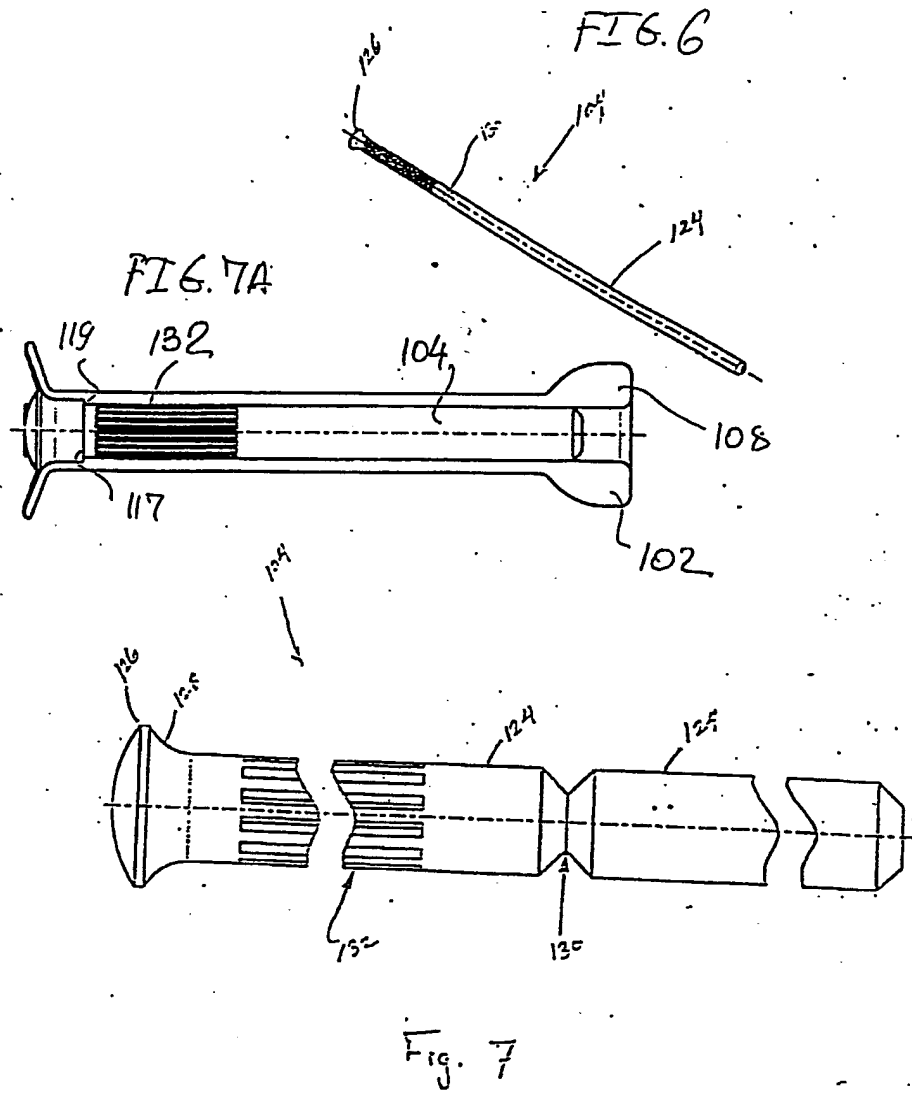
6 expand a weakened portion of the rivet, so that the expanded weakened
7 portion engages the one vertebra, and break off into distal and proximal ends after the one
8 of the adjacent vertebra is engaged in the second mode of operation of the crimping
9 assembly; and
10 have the proximal end removed from the crimping assembly in the third
11 mode of operation.

1
1 49. The kit of claim 47, wherein the mandrel and the hollow rivet have each a
2 respective straight body or a curved body.

1
1 50. The kit of claim 47, further comprising an instrumentation/implant case
2 containing the plurality of rivet assemblies, implants and the crimper assembly, the
3 weakened portion of the rivet being provided either on the distal portion of the hollow
4 rivet or a distance from the distal portion.







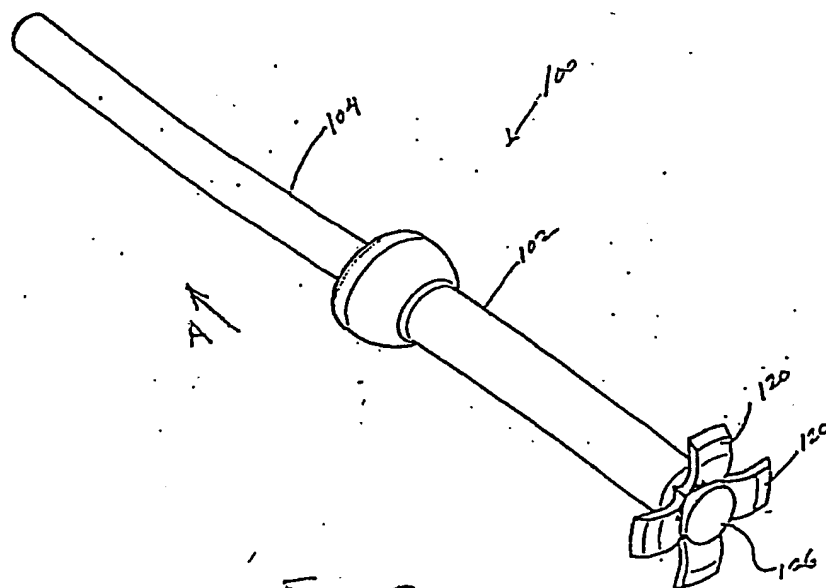


Fig. 8

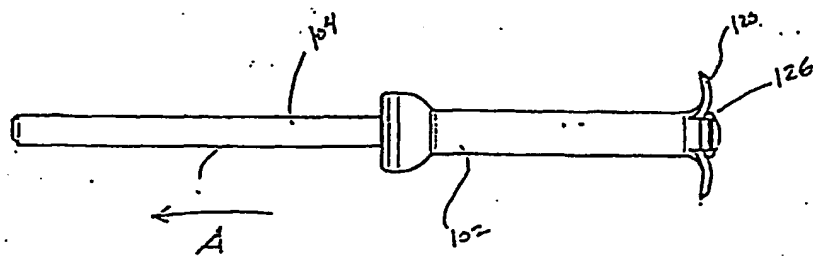


Fig. 9

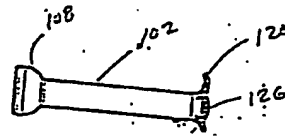
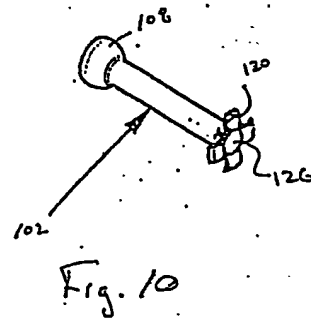
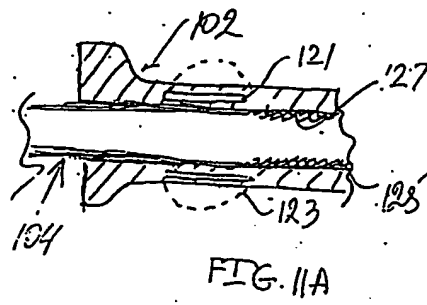
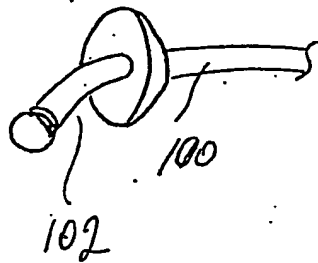


FIG. 11B



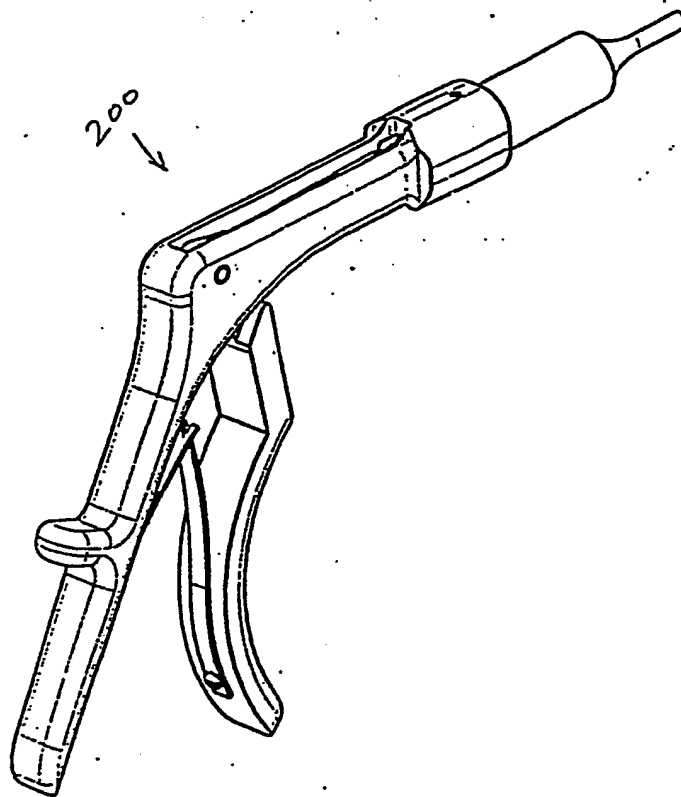


Fig. 12

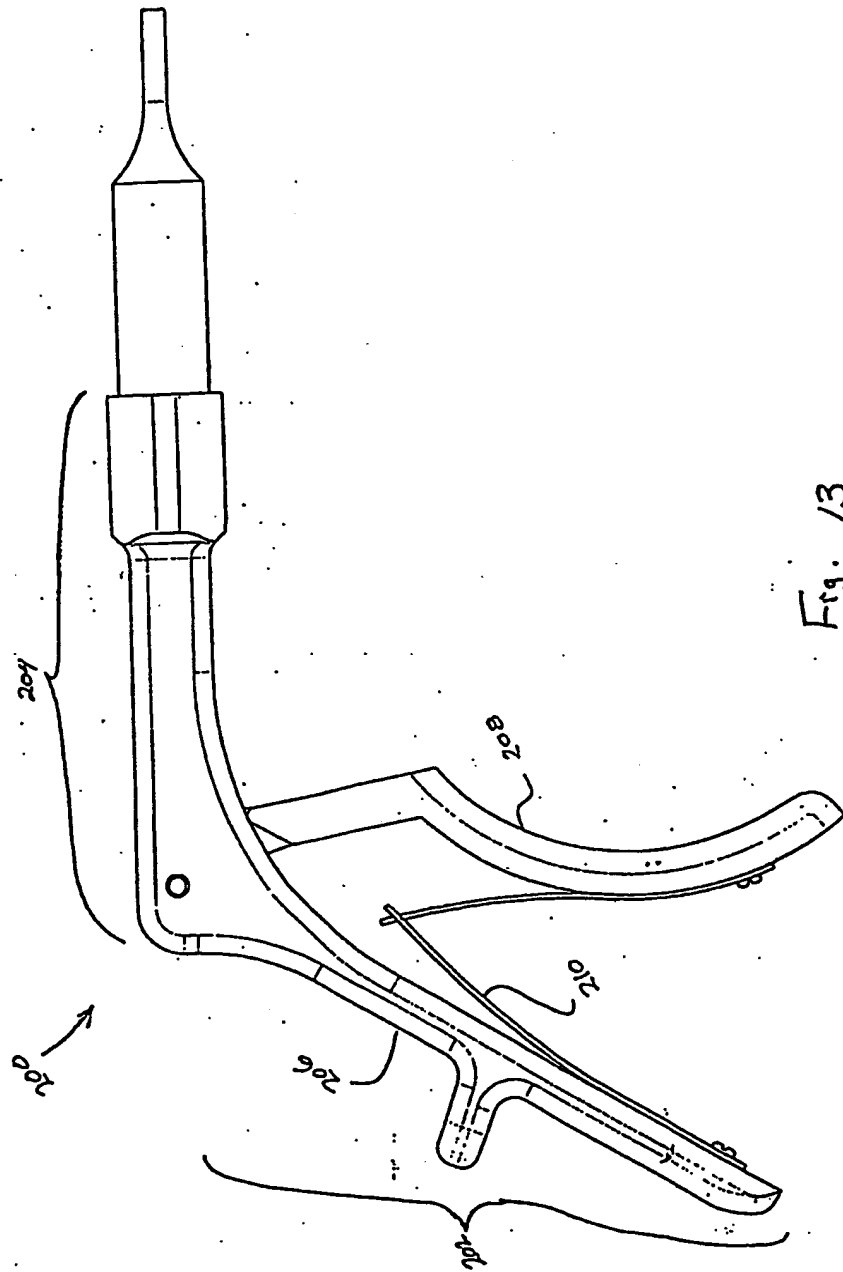
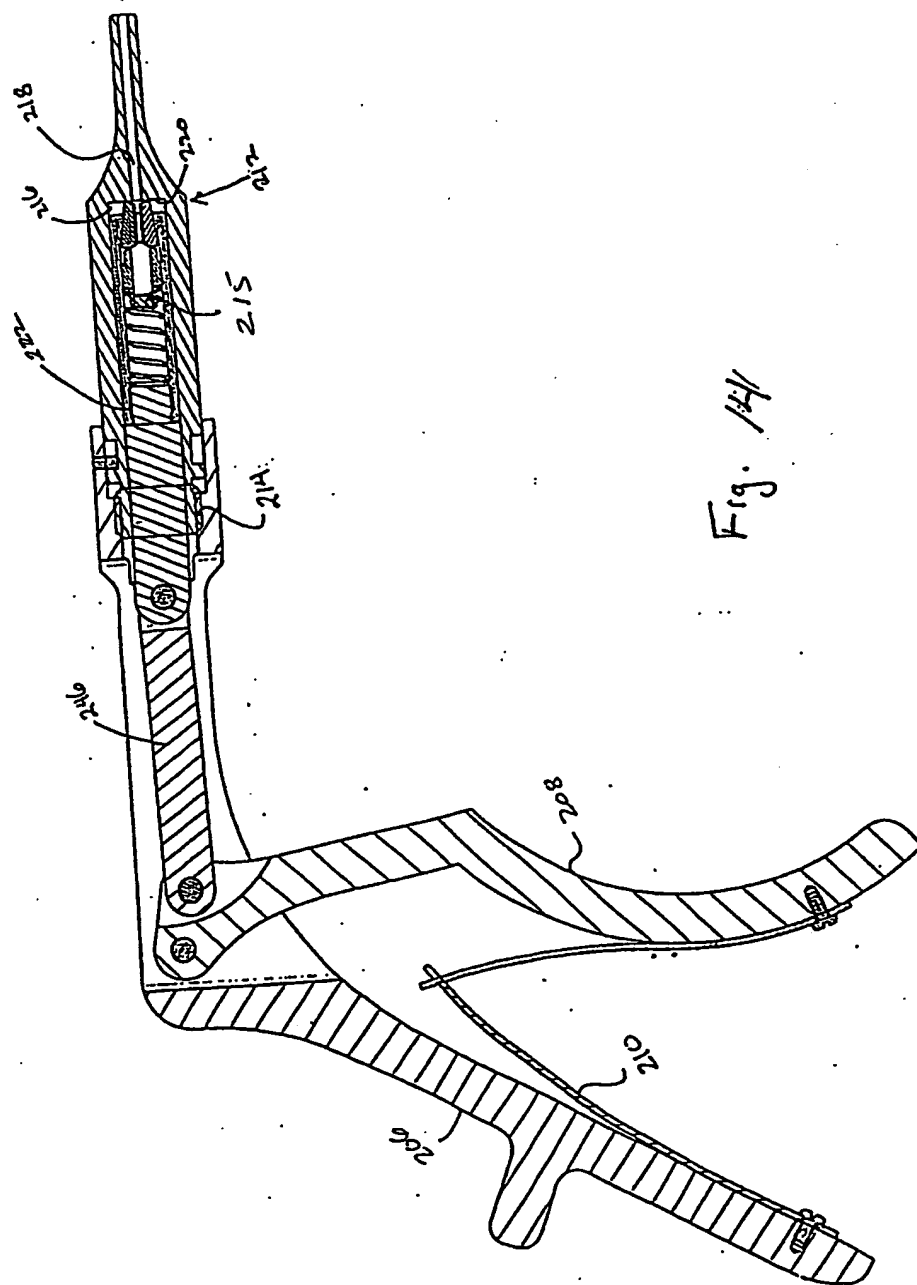


Fig. 13



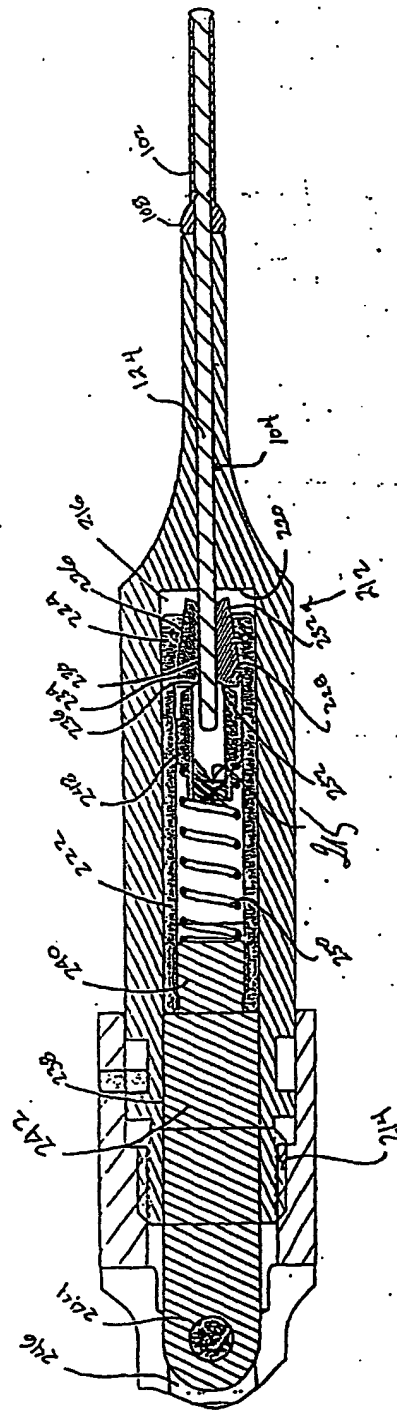


Fig. 15

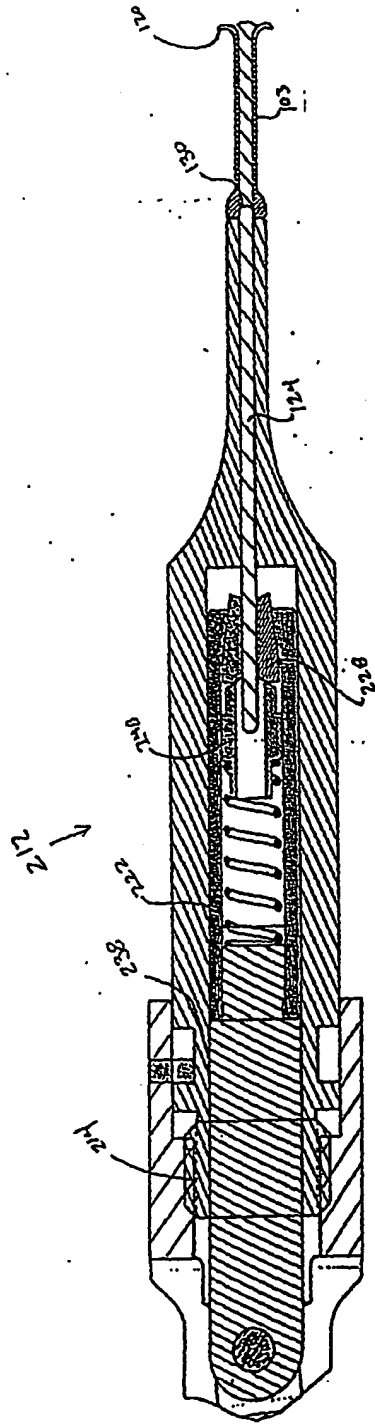


Fig. 16

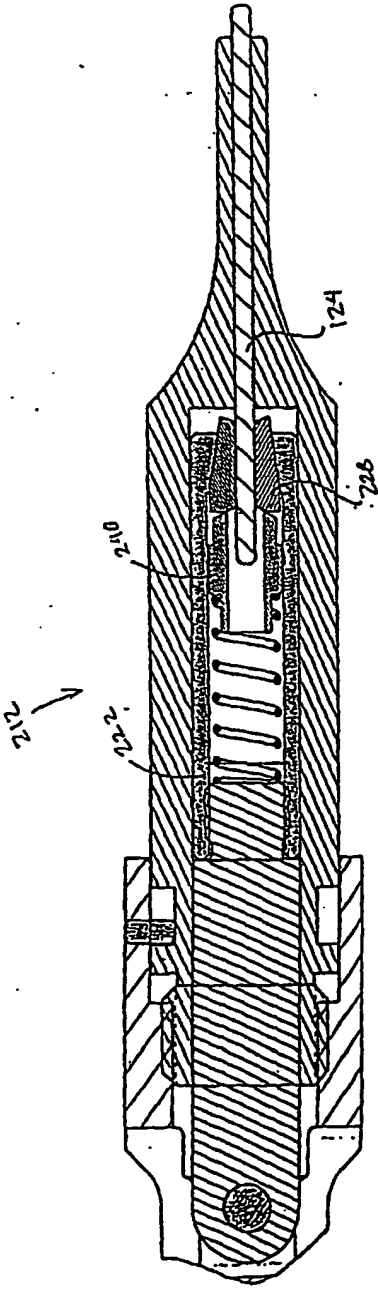


Fig. 17

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 02/41438

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/68 A61B17/04 A61B17/068 B21J15/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B B21J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 571 686 A (ANSPACH WILLIAM E JR ; REID WILLIAM S (US); DEL RIO EDDY H (US)) 1 December 1993 (1993-12-01)	7-20
Y	abstract; figures 1,2,13 column 1, line 46-56 column 4, line 22-27,40-44 ---	21-31
X	US 4 355 934 A (DENHAM KEITH ET AL) 26 October 1982 (1982-10-26)	7-20
A	abstract; figures 1,2 column 3, line 45 -column 4, line 40 ---	40-44, 48,49
X	FR 2 738 142 A (CEDIOR) 7 March 1997 (1997-03-07)	7
A	abstract; figure 1 page 3, line 17-20,27-32 page 4, line 1-4 ---	
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

31 March 2003

Date of mailing of the international search report

04/04/2003

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INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 02/41438

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 167 665 A (MCKINNEY WILLIAM W) 1 December 1992 (1992-12-01) abstract; figures 1,3 column 2, line 15-37 ---	7
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/41438

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-6
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

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PCT/US 02/41438

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